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UNITED STATES DISTRICT COURT
DISTRICT OF OREGON

UNITED STATES OF AMERICA

v.

BRENDA ROBERTS ,

Defendant.

3:18-cr-00246-BR

**GOVERNMENT'S SENTENCING
MEMORANDUM**

**Sentencing: October 4, 2018
at 11:00 a.m.**

The United States of America, by and through its attorneys, Billy J. Williams, United States Attorney for the District of Oregon, and Donna Brecker Maddux, Assistant United States Attorney, submits this memorandum for the benefit of the Court and the parties in preparation for the sentencing hearing in this case. Sentencing is scheduled for Thursday, October 4th at 11:00 a.m. before the Honorable Anna J. Brown.

I. STATUS OF THE CASE

On June 19, 2018, the defendant waived Indictment and entered a guilty plea to a one-count Information charging her with the receipt of foreign sourced Botox and foreign sourced

Juvaderm in interstate commerce and proffered both for delivery and pay in violation of 21 U.S.C. § 331(c), a class A misdemeanor.

II. FACTUAL BACKGROUND

Defendant was a licensed medical doctor in the State of Oregon between 1998 and July 2018. In July 2018, via a stipulated order before the Oregon Medical Board, the defendant surrendered her Oregon medical license pending the completion of the Medical Board's investigation. The Medical Board's investigation stemmed from federal civil and criminal investigations of defendant's home office medical practice. In the stipulated order, the Medical Board found the defendant engaged in unprofessional or dishonorable conduct, repeated negligence, and violations of the Controlled Substances Act.

As a supplement to her full-time position with an outside medical practice, the defendant provided medical services from her home office in Troutdale, Oregon since at least 2008. The Drug Enforcement Agency (DEA) investigated the defendant for dispensing controlled substances over the internet and without a valid prescription from her home office. Defendant resolved these claims via a monetary civil settlement with the United States Attorney's office Civil Division in May of 2018.

During their investigation, the DEA learned that the defendant administered Botox to patients at her home office. The DEA, concerned about the potential importation of foreign sourced and unapproved Botox, referred the Botox claims to the Food and Drug Administration, Office of Criminal Investigations (FDA-OCI).

The United States Food and Drug Administration (FDA) is the federal agency charged with the responsibility of protecting the health and safety of the American public by enforcing

the Food, Drug and Cosmetic Act (“FDCA”). Among the purposes of the FDCA is to ensure that medical products, including drugs, biologics, and devices, sold for human consumption or administration, are safe, effective, bear labeling containing only true and accurate information, and have adequate directions for use. The FDA’s responsibilities under the FDCA include regulating the manufacture, labeling and distribution of all drugs, biologics, and medical devices shipped or received in interstate commerce, including Botox and Juvederm.

Botox and Juvederm are manufactured by Allergan and are supplied to health care providers through Allergan’s closed delivery system. If a health care provider purchases Botox or Juvederm from an authorized distributor, the order is fulfilled by Allergan and the product is shipped directly from Allergan to the health care provider. This process allows Allergan to control and track all Botox and Juvederm supplied to health care providers. The investigation revealed that the defendant did not purchase legitimate FDA approved Botox or Juvederm from Allergan or one of its authorized distributors after May 2008. Allergan closed the defendant’s account in 2008 when Allergan realized the defendant shipped the product to a residential address. Allergan’s policies prohibit shipping drugs and devices to residential addresses.

Practitioners in the United States can purchase drugs and medical devices intended for distribution in foreign countries and not approved by the FDA for use in the United States. Practitioners make these purchases from rogue internet wholesalers, some of whom obtain these products by illicit methods, including theft from the foreign supply chain. Use of these products creates potential health risks. It is impossible for the practitioner or end-user to confirm the authenticity of such product.

The investigation revealed that the defendant purchased unapproved products from BuckADayPharmacy.com, AllDayChemist.com and FinlandiaPharmacy.com, among others. The investigation revealed that all product obtained by the defendant after May 2008 was not approved for use in the United States but was instead manufactured for distribution in foreign countries, including but not limited to the European Union, Australia, Iran, and Mexico.

FDA-OCI reviewed defendant's patient files and interviewed a sample of patients who received the unapproved Botox and Juvaderm. None of the patients reported unanticipated adverse side effects or reactions.

III. THE PRESENTENCE REPORT

The presentence report (PSR) appears to have accurately calculated the following applicable advisory sentencing guideline provisions:

- 1) **Base Offense Level**: Pursuant to U.S.S.G. § 2N2.1.1(a), the base offense level is six (6).
- 2) **Acceptance of Responsibility**: Pursuant to U.S.S.G. § 3E1.1(a), the offense level should be reduced two (2) levels for defendant's acceptance of responsibility. This should result in a Total Offense Level of four (4).
- 3) **Criminal History Category**: Pursuant to U.S.S.G. § 4A1.(1), and the table at Chapter 5, Part A, defendant's criminal history score is three (3) and the applicable criminal history category is II.

IV. SENTENCING RECOMMENDATION

Defendant's Criminal History Category of II, combined with a Total Offense Level of four (4), results in an applicable advisory sentencing guideline range of zero (0) months – six (6) months

in Zone A. Consistent with the terms of plea agreement, the United States recommends the Court sentence the defendant to serve six (6) months of probation, to be terminated after the completion of 40 hours of community service as condition of probation, along with the \$25 special assessment.

Considering the nature and circumstances of the offense, the history and circumstances of the defendant, and the kinds of sentences available, the recommended sentence is sufficient, but not greater than necessary, to comply with the purposes of sentencing set forth in 18 U.S.C. § 3553(a). This recommendation reflects the seriousness of the offense, promotes respect for the law, provides just punishment for the offense, affords adequate deterrence to criminal conduct, and protects the public from further crimes of the defendant.

The collateral consequences of defendant's conduct, including the Medical Board action, the civil settlement, and the absence of patient harm factor prominently in the government's negotiated resolution of the criminal FDCA charge.

V. CONCLUSION

For the above reasons, the United States recommends the Court sentence the defendant to serve six (6) months of probation, terminated after the completion of 40 hours of community service as a condition of probation, along with the \$25 special assessment.

Dated: September 26, 2018

Respectfully submitted,

BILLY J. WILLIAMS
United States Attorney

s/ Donna Brecker Maddux

DONNA BRECKER MADDUX, OSB #023757
Assistant United States Attorney